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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,829	11/29/2001	Ji Won Yoon	1546.1007	9726

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,829

Applicant(s)

YOON ET AL.

Examiner

Myron G. Hill

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1- 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1- 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 6) ☒ Other: **RAW SEQUENCE ERROR REPORT**.

DETAILED ACTION

Response to Arguments

This action is in response to Amendment A, paper 6, filed 1 July 2002 as well as Sequence Listing and Deposit Declaration. Claims 1- 11 are under consideration in this office action.

SEQUENCE COMPLIANCE

Applicant has submitted a CFR, sequence listing, and letter but has not fully complied with the sequence rules, because the sequence disk contains format errors, please see attached sheets and has not fully complied with the sequence rules, see 37 CFR 1.821(d) pertaining to the requirement that all instances in the description and claims disclosed sequences must be identified by a SEQ ID#.

Response to Amendment

The arguments from Applicant have been considered and found persuasive in part. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

Rejections Withdrawn

The rejections under USC 112, second paragraph and the objection to claim 3 are withdrawn because they are moot in light of the amendments.

Rejections Maintained

Claim Rejections - 35 USC § 112

The rejection under USC 112, first paragraph, for Deposit Requirements is maintained. The declaration refers to "the deposit" without identifying the deposited material. A declaration or a attorney's statement which refers to the deposited strain, ATCC- UR-1354, would overcome the rejection.

Claim Rejections - 35 USC § 103

Claims 1- 3 and 7- 11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Muir et al. (US Patent 5,891,435).

Applicant argues that Muir only discloses that vaccinia virus is used to express numerous viral antigens, that the specific cloning of GAD 65 was not disclosed, and that the suitability of a virus to express antigens should be tested.

The argument of Applicant have been fully considered and not found persuasive.

It is further noted that Muir teaches the following in the specification that was used:

Muir teaches subjects develop autoantibodies to GAD65 when they develop IDD (column 3, lines 25- 34), other researchers have tried antigen specific therapies and explained why they work (column 9, lines 18- 28 which precedes the specific mention of GAD65, column 9, lines 29- 31 as cited above), and lists specific antigens that can be used to prevent or ameliorate autoimmune disorders including GAD as a therapeutic autoantigen (column 9, line 61- column 10, line 13 and Table 1).

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Thus, there is specific reference to the use of GAD65 as a therapeutic agent.

In addition, the level of skill in the art of making vaccinia recombinants is high and is routine lab work especially since the sequence of GAD was known in the art; therefore, specific teaching of clone construction would not be needed. Rejection maintained.

Claims 4-6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Muir as applied to claims 1-3, and 7- 11 above, and further in view of Moss (Moss et al. Nucleic Acids Research 1990, 18:4285- 4286).

Applicant argues that the specific molecule is not taught and that success of the specific combination cannot be expected without extensive experimentation.

The argument of Applicant have been fully considered and not found persuasive.

As stated above, the sequence of GAD65 was known in the art and the level of skill in the art of making vaccinia virus recombinants is high and making constructs, even though time consuming, is routine lab work. Specific cloning directions would not be needed and screening for good clones would not be considered extensive experimentation. Rejection maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill
Patent Examiner
September 29, 2002


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1808
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